

Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants

**SOPP 8101.1
Appendix 2**

Example of the Official Meeting Summary



FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

MEMORANDUM

DATE:

FROM: *Point of contact, division, HFM number*

TO: *The file (file identifying information/number)*

SUBJECT: *Summary of type meeting*

Meeting Date:

Time:

Location:

Meeting Requestor/Sponsor:

Type of meeting: (e.g., Pre-IND, End of Phase 2, pre-PLA, RTF, Protocol Assessment, Compliance, Promotion)

CBER Meeting Leader:

Recorder:

FDA Attendees:

Sponsor Attendees:

Meeting Objectives: *include list of questions from meeting request*

Discussion Points:

Decisions/Agreements Reached:

Issues Requiring Further Discussion:

Action Items:

Attachments/Handouts: